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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,250	08/21/2001	Wenbin Dang	GPT-029.01	6514

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,250

Applicant(s)

DANG ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed March 4, 2004 have been entered.

Claims 1-41 are pending.

The outstanding rejections under 35 USC 112, second paragraph with regard to biocompatible oils having specific physical characteristics are withdrawn in view of the remarks filed March 4, 2004.

The outstanding rejection under 35 USC 102 over Takagishi et al. is withdrawn in view of the remarks filed March 4, 2002.

The outstanding rejection under 35 USC 103 over Takagishi et al. is withdrawn in view of the remarks filed March 4, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-31, and 34-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for biocompatible oils recited in claim 3, does not reasonably provide enablement for other biocompatible oil. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue

experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that define "biocompatible oil" other than just disclosed "biocompatible oil" as oil that is not known to be toxic. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these oils without undue experimentation. In the instant case, only a limited number of "biocompatible oil" examples are set forth, thereby failing to provide sufficient working examples. Examiner notes that some oils, for example, mineral oil, is not toxic when ingested, but very harmful if it is inhaled, which would cause lipid pneumonia (See Remington's Pharmaceutical Sciences, 18th ed., 1990, page 788). So according to the criteria disclosed in the specification, mineral oil is considered biocompatible because it is *per se* non-toxic. However, it

is not suitable for use in the invention because of its potential to cause pneumonia. Therefore, without guidance as to selecting suitable oil, one of skilled in the art would be required to assess each embodiment individually for physiological activity. The instant claims are so broad that read on all "biocompatible oil(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-18, 21, 23, and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-18, 21, 23, and 28-29 recite the limitation "said biocompatible oil, and all other biocompatible oils" in 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 merely recites "a biocompatible oil".

Response to arguments

Applicant's rebuttal arguments filed March 4, 2004 averring the limitation "all other biocompatible oils" not requiring antecedent basis have been considered, but are not found persuasive. Examiner notes that the "all other biocompatible oils" are additional components that were not recited in the base

claim. Applicant is recommended to use phrases such as "further comprising" or "optionally further comprising" in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 27-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Samejima et al. (JP 10001441, English abstract is provided).

Samejima et al. teaches a local anesthetic composition may contain lidocaine and sesame oil, which is in an oil mixture in an amount of 70-100% (See the abstract).

Claims 1-19, and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 2,625,501 (herein after as '501).

'501 teaches a parenteral composition comprising sesame oil and cotton seed oils in about 98% of the composition and about 2% of morphine sulfate salt (See col. 1, lines 7-14, 23-34, and col. 2, lines 18-30). '501 also teaches the morphine sulfate-containing-composition can be formulated into an ampoules (See col. 2, lines 40-41).

Claims 1-12, 27, and 30-38 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,105,793 (herein after as '793).

'793 teaches a parenteral composition containing lidocaine hydrochloride (See claim 5).

Examiner notes that the printed instructions recited in the claims lend no patentable weight to claims that drawn to composition because they do not impart a structure-functional relationship to the herein claimed composition.

Response to arguments

Applicant's arguments filed March 4, 2004 averring Samejima et al. not teaching a composition suitable for parenteral administration have been considered, but are not found persuasive. Examiner notes that the composition of Samejima et al. possesses the exact same components as that recited in the claims. Limitation drawn to the intended use does not lend any patentable weight in the claims drawn to composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over '501 as applied to claims 1-19, and 34-41 above.

'501 teaches a parenteral composition comprising sesame oil and cotton seed oils in about 98% of the composition and about 2% of morphine sulfate salt (See col. 1, lines 7-14, 23-34, and col. 2, lines 18-30). '501 also teaches the morphine sulfate-containing-composition can be formulated into an ampoules (See col. 2, lines 40-41).

'501 does not teach the amount of the salt of analgesics as at least 3% or 4%, 10%, or 40% in weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the weight ratio of the analgesic salt component in '501 to the herein claimed amount.

One of ordinary skill in the art would have been motivated to adjust the weight ratio of the analgesic component in '501 to the herein claimed amount. The optimization of result effect parameters (e.g., dosage regimens) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over '793 as applied to claims 1-12, 27, and 30-38 above.

'793 teaches a parenteral composition containing lidocaine hydrochloride (See claim 5).

'793 does not expressly teach the weight ratio of the oil components in the composition as at least 50% or 85%.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the weight ratio of the oil components in '793 to the herein claimed amount.

One of ordinary skill in the art would have been motivated to adjust the weight ratio of the oil components in '793 to the herein claimed amount. The optimization of result effect parameters (e.g., the amount of the carrier) is obvious as being within the skill of the artisan especially when formulate a liquid composition for parenteral use employing the oil as a carrier materials, absent evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to rejection under 35 USC 103 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is

(571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu
- Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the
examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571)
272-0629. The fax phone number for the organization where this application or
proceeding is assigned is 703-872-9306.

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-
free).

San-ming Hui
Patent Examiner
Art Unit 1617

A handwritten signature in black ink, appearing to read 'San-ming Hui', is written over the printed name and title.